UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FRANCIS FENWICK, EDWARD SAFRAN, STEVE HARDING, MARY WARDRETT, AND LINDA YOUNG, Individually and on behalf of all others similarly situated, Plaintiffs, vs. RANBAXY PHARMACEUTICALS, INC., RANBAXY LABORATORIES, LTD., RANBAXY LABORATORIES, INC., RANBAXY, INC., RANBAXY USA, OHM LABORATORIES, EXPRESS SCRIPTS INC., EXPRESS SCRIPTS HOLDING COMPANY, MEDCO HEALTH SOLUTIONS, INC., ABC CORPORATIONS 1-10, AND JOHN DOES 1-10, Defendants.	Civil Action No.: 3:12-CV-07354-PGS-DEA

PLAINTIFFS' MEMORANDUM OF LAW IN REPLY TO DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION DIRECTING DEFENDANTS TO CONDUCT A TOTAL PRODUCT RECALL AT THE CONSUMER/PATIENT LEVEL

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PRELIMINARY STATEMENT[1]

The defendants would like the Court to believe that the recall of the adulterated Atorvastatin involves complex scientific, medical and technical issues that are beyond the Court's expertise. They maintain that an "intense medical analysis" must be conducted in order to understand the health issues. The defendants must take that position in order to support their argument that the doctrine of primary jurisdiction prohibits this Court from taking any action related to the recall. However, their argument falls apart when the cases they rely on are compared to this matter.

The cases cited by the defendants (*Clark, Human Tissue*, and others) involved requests by the plaintiffs that the Court write its own notice that went beyond the notice issued by the FDA and which provided additional medical warnings and information. Essentially, the plaintiffs in those cases argued that the FDA notices about the recalls were insufficient. In this case, the plaintiffs are not asking for such drastic relief. The plaintiffs simply want the recall to be broadened from the retail level to the consumer level.

The defendants, not the FDA, initiated the recall and they could have made it a consumer level recall. They chose not to do so.[2] When the FDA was notified, they began their investigation, which is ongoing. The plaintiffs' request to broaden the recall to the consumer level is not "second-guessing the FDA". It is within the Court's inherent power to broaden the recall and doing so will have no impact on the FDA's involvement with the defendants' recall of its product. The defendants' adulterated pills contain glass particles and simple common-sense and reason dictate that the pills should be removed from the public.

In addition, after the plaintiffs' motion was filed, another reason arose for broadening the recall to the consumer level. The defendants announced on February 22, 2013 that they have resumed

[1] The Ranbaxy defendants and the Express Scripts defendants submitted separate opposition papers but the arguments are very similar. Therefore, this Memorandum of Law will not reply separately to the two sets of opposition papers.

[2] It appears from their opposition papers that they limited the recall to the retail level to avoid expenses and possible damage to their reputation. It is ironic indeed that they are concerned about their reputation when the FDA already determined a year ago that the defendants lied, falsified documents and submitted false data. In addition, the defendants have a long history of quality problems and other issues with their products made overseas and sold in the United States.

production of the Atorvastatin pills. Thus, in the near future, there will be additional pills in the public and the likelihood for confusion will be high.[3] A full recall will address that problem.

LEGAL ARGUMENT

I. THE DOCTRINE OF PRIMARY JURISDICTION IS INAPPLICABLE

The plaintiffs do not dispute that the doctrine of primary jurisdiction is frequently applied to drug recall cases, such as the *Clark* case and the *Human Tissue* case that the defendants rely on. *Clark v. Actavis Group hf, 567 F. Supp. 2d 711 (D.N.J. 2008)*; *In re Human Tissue Products Liability Litigation, 488 F. Supp. 2d 430 (D.N.J. 2007)*. The Courts that have applied the doctrine of primary jurisdiction have deferred to the FDA because the cases involved scientific, technical and/or medical issues that are outside the ambit of conventional judicial experience. In fact, whether a case involves such novel, complex issues is one of the four factors that Courts consider when determining whether the doctrine of primary jurisdiction is applicable. When those four factors are applied to this case, it is clear that the doctrine is not applicable. Instead, the plaintiffs' request to broaden the recall is within the Court's inherent power.

To determine whether the doctrine of primary jurisdiction is applicable, a court must consider the following factors:

> (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise;
> (2) whether the question at issue is particularly within the agency's discretion;
> (3) whether there exists a substantial danger of inconsistent rulings; and
> (4) whether a prior application to the agency has been made.

Clark v. Actavis Group hf, 567 F. Supp. 2d 711, 715 (D.N.J. 2008), citing *IPCO Safety Corp. v. WorldCom Inc. 944 F. Supp. 352, 356 (D.N.J. 1996)* (quotation omitted).

[3] As is discussed below, the FDA notifies recalling firms by letter that the chance of accidental use increases the more time that passes between the recall and removal/destruction of the adulterated product. In addition, the FDA has argued for the removal of adulterated pills from the public. *See discussion, infra.*

With respect to the first factor, the plaintiffs' request to broaden the recall to the consumer level does not involve any technical or policy considerations that are solely within the FDA's particular field of expertise. Broadening the recall does not involve novel or complex scientific and medical information. It would not require an intense medical analysis by the Court. The reason to broaden the recall to the consumer level is very simple: the product is adulterated (the defendants' have admitted that the pills contain glass particles) and it makes perfect sense to remove it from the public before more harm occurs.

The request for injunctive relief is not based on a new scientific study, data or finding that the plaintiff wants the public to be aware of. It seeks only to protect the health and safety of the class by removing the adulterated drug from the public. In the *Clark* case, the FDA submitted an Amicus Brief which made the same arguments that the plaintiffs are making herein. The FDA opposed the plaintiffs' request in *Clark* for an additional notice to the class, which contained different medical information from the FDA's first notice.[4] (A copy of the FDA's Amicus Brief is attached to the Gainey Reply Declaration as Exhibit "O".) In their Amicus Brief in *Clark*, the FDA made the following statement, which is particularly applicable to this case:

> More fundamentally, however, plaintiffs' requested instruction that patients retain the defective drug product is contrary to the essential public health purpose of a recall – the removal of violative (and potentially harmful) drugs from commerce and from patients' medicine cabinets. Many of the patients who were prescribed Digitek are likely still in need of similar medication, and patients who retain super-potent Digitek may inadvertently ingest it. Although FDA recognizes the inherent authority of a Court to order that parties to litigation preserve evidence in their possession, custody or control, FDA believes that patients should not be directed to retain products that are subject to a recall.
>
> *FDA's Amicus Brief in Clark, at Page 3-4* (See Exhibit "O" to Gainey Reply Declaration).

[4] It is particularly telling that the FDA submitted Amicus Briefs in *Clark* and other cases but they have not done so in this matter. *See Clark, supra, and Bernhardt. Bernhardt v. Pfizer, 2000 WL 1738645 (SDNY November 22, 2000)* (A copy of the unpublished decisions cited in plaintiffs' reply papers is attached in the Gainey Reply Declaration as Exhibit "U".)

As can be seen, the FDA views removal of adulterated product from the public as being of critical importance to public safety.

The plaintiffs are not questioning the safety and effectiveness of unadulterated Atorvastatin. Likewise, there is no request that the Court change the language chosen by the FDA concerning the dangers involved with the adulterated pills. Instead, the plaintiffs simply want the adulterated pills removed from the public, which the FDA has made clear they support in their form letters to recalling firms and in their Amicus Brief in *Clark*.

To be clear, the plaintiffs do disagree with the FDA's position, especially when it reversed itself on whether the public can keep taking the adulterated pills. (See Exhibit "E" to the Declaration of Barry J. Gainey in Support of the Plaintiffs' Initial Motion.) However, the plaintiffs are not requesting a notice to the public that contains any new or different medical information beyond that contained in the existing FDA statements. Plaintiffs simply want the adulterated product removed from the public. The removal of the adulterated pills is even more important and time-sensitive now that the defendants have announced that they resumed production of Atorvastatin. It would certainly boost consumer's confidence in the safety of the new pills if the adulterated ones are completely removed from the public and destroyed. There would be no chance of confusion or inadvertent ingestion.

The defendants rely on Judge Martini's decision in *In re Human Tissue Products Liability Litigation, 488 F. Supp. 2d 430 (D.N.J. 2007) ("Human Tissue")*. However, the *Human Tissue* case is factually distinguishable from this case. It did not involve a prescription drug let alone an adulterated one. Rather it involved the harvesting of unscreened and potentially diseased, infected human tissue from corpses without proper consent. The plaintiffs in *Human Tissue* wanted an additional notice sent to the class with new and different medical warnings and information. Here, the broadened recall does not involve a communication to the class about the need for testing as the proposed notice in *Human*

Tissue. Rather, the plaintiff simply wants to broaden the recall and remove the product from the hands of the public.

Thus, the first factor supports a finding that the doctrine of primary jurisdiction is not applicable to this matter.

With respect to the second factor to be considered when deciding whether the doctrine of primary jurisdiction applies, the plaintiffs' request to broaden the recall to the consumer level is not an issue that is "particularly within the agency's discretion". See *Clark, supra, 567 F. Supp. 2d at 715*. The plaintiffs are not asking the Court to override the FDA or disseminate new or different medical information to the public. The plaintiffs acknowledge that the FDA has issued two notices concerning the adulterated product and the plaintiffs acknowledge that deference should be given to their position while their investigation continues.[5] However, the recall can be broadened to the consumer level without having any effect on the FDA investigation or their position on the likelihood or severity of injury from ingesting the adulterated product.

The recall was initiated by the defendants as opposed to ordered by the FDA.[6] The FDA classified the defendant's recall as a Class II recall.[7] The FDA classified the recall based on the

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[5] As noted above, the plaintiffs do disagree with the FDA's position and plaintiffs criticize the FDA's contradictory statements of November 29th and November 30th. However, those issues are not involved with the plaintiffs' request for injunctive relief.

[6] Shockingly, the defendants have not provided this Court with a single document or Declaration from the defendants concerning the recall, the cause of the adulteration, what was done to correct the problems, or what the FDA has told the defendants. Instead, the defendants submitted news articles to support their statements about their own recall and subsequent investigation.

[7] The classifications are as follows:

> Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.
>
> - **Class I recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
> - **Class II recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
> - **Class III recall:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
> - **Market withdrawal:** occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

information provided by the defendants, which included their claim that they had no reports of adverse health events.

The defendants initially informed the FDA that they had no reports of adverse health events, but later they learned of at least one incident. Thereafter, there were more than 50 reports to the FDA of adverse health events.[8] The FDA is investigating the injury reports and will not issue an updated statement until that is completed. The plaintiffs disagree, once again, with the FDA and believe that the delay is unnecessary. However, even accepting the FDA's delay, the Court can still broaden the recall to the consumer level. The FDA's investigation of the scores of adverse health reports includes the issues of causation, the likelihood of injury, and the severity of injury. On the other hand, this Court is not engaged in that analysis. This Court considers the legal issues involved with the plaintiff's request for an injunction, which includes the four factors that are addressed in plaintiff's initial Memorandum of Law as well as below in Point III. The point here is that the FDA's focus is different from this Court's focus and, in fact, the Court and the FDA have different roles. This Court can broaden the recall to the consumer level to remove the adulterated pills from the public without interfering with or affecting the FDA's investigation and its role in the process. The FDA classified the recall based on the lack of reported injuries and they will not change that until they investigate the 50 reports. However, the Court can order the product be removed from the public immediately.

Thus, this second factor supports a finding that primary jurisdiction is not applicable to this matter.

- **Medical device safety alert:** issued in situations where a medical device may present an unreasonable risk of substantial harm. In some cases, these situations also are considered recalls.

[8] Amazingly, the defendant's website has not been updated concerning the dozens of reported adverse health events. Their November 28th statement is still on their website, which provides grossly inaccurate information to consumers by misrepresenting that "Ranbaxy has not received any reports of adverse health events". The current "update" on their website states that they have resumed production but the update is silent on the more than 50 reported adverse health events or any health issue whatsoever. (See Exhibit "S" attached to the Gainey Reply Declaration.)

With respect to the third factor to be considered when deciding whether the doctrine of primary jurisdiction applies, the plaintiffs' request to broaden the recall to the consumer level does not create a "substantial danger of inconsistent ruling". *See Clark, supra, 567 F. Supp. 2d at 715.* The plaintiffs are not asking the Court to disseminate new medical information. Indeed, that is a critical difference between the relief requested herein and the relief requested in *Clark, Human Tissue* and *Bernhardt.* As the *Clark* Court noted, those three cases share the common issue of "what is appropriate dissemination of medical information to the consuming public?" *See Clark, supra, 567 F. Supp. 2d at 716.* In those three cases, the plaintiffs were requesting that notices be sent out to the public that contained new and/or different medical information from the first FDA approved notice.[9] This case is very different because the plaintiffs do not want the Court to disseminate new medical information but instead they simply want to broaden the recall to the consumer level to remove the adulterated pills from the public.[10]

Thus, the third factor supports a finding that the doctrine of primary jurisdiction is not applicable to this matter.

The fourth factor of whether there has been a prior application to the FDA does not have an impact in this matter. As the *Clark* Court noted, the fact that the plaintiffs did not file an application with the FDA is not dispositive. *Clark, supra, 567 F. Supp. 2d at 719.* The FDA has 180 days to respond to a Citizens Petition filed pursuant to *21 C.F.R. § 10.30.* The plaintiffs are seeking relief from this Court because the Court can act much sooner than 180 days, the Court has the inherent power to grant the relief requested, and the Court can immediately act to protect the public.

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[9] Ranbaxy's counsel, Mr. Patunas, represented the plaintiffs in the *Clark* case and argued that primary jurisdiction did not apply.

[10] The adulterated product will not be "brought into compliance" and so the defendant's argument that it should remain in the public is puzzling since it will serve no purpose. In fact, it will actually create a "greater chance of its accidental misuse". See FDA Regulatory Procedures Manual – July, 2012, Chapter 7, Recall Procedures, Exhibit 7-7, FDA Model Letter to recalling firm. (A copy is attached to the Gainey Reply Declaration as Exhibit "T".) See also the FDA's Amicus Brief in the *Clark* case. (A copy is attached to the Gainey Reply Declaration as Exhibit "O".)

Thus, all the factors bearing on whether to apply the doctrine of primary jurisdiction counsel against applying the doctrine. The Court can grant the injunctive relief while the FDA continues to perform its duties relating to the recall. The FDA will decide when the defendants have corrected their manufacturing problems and can sell to consumers in the United States again, if ever again.[11] The Court will not be "second-guessing" the FDA by granting the injunctive relief. Instead, the Court and the FDA will be performing their respective duties on parallel courses and the public will be safe from the harm that could be caused by the adulterated pills.

II. DESPITE DEFENDANTS' ARGUMENT TO THE CONTRARY, THE "FINAL RELIEF" REQUESTED IN THE PLAINTIFF'S COMPLAINT IS MUCH BROADER THAN THE INJUNCTIVE RELIEF REQUESTED IN THIS MOTION

The defendants' argument that granting injunctive relief would be tantamount to granting the final relief requested in the pleadings ignores most of the plaintiffs' Complaint. The plaintiffs' Complaint seeks: (1) an Order certifying the class and naming class counsel; (2) compensatory damages to the plaintiffs and class members; (3) treble damages and attorney's fees (which are mandatory under the New Jersey Consumer Fraud Act); (4) disgorgement of ill-gotten gains; and (5) equitable and injunctive relief, including a total product recall, notice to consumers, refund to customers, replacement product for customers and/or other relief. It is clear that the "final relief" requested by the plaintiffs involves much more than the injunctive relief requested in this motion. Even the items listed in plaintiff's Complaint as being part of the "equitable and injunctive relief" are much greater than the injunction sought in this motion. The differences between the relief sought in this motion and the final relief on the merits is clear.[12]

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[11] Of course, in this particular case, the FDA may also consider the defendants long history of violations and failures to comply with the FDCA as well as the defendants prior lies and falsifying of documents and data.

[12] The defendants' argument begs the question: if the plaintiffs' Complaint did not request injunctive relief, would the defendants now be arguing that injunctive relief was not requested in the Complaint and so the Motion must be denied?

The defendants also argue that if injunctive relief is granted and then they win on the merits, the injunctive relief cannot be reversed. The argument fails for several reasons. First, the plaintiff's likelihood of success on the merits is one of the factors that the Court considers when deciding a motion for preliminary injunction. The reason that it is one of the factors is because of the "irreversible" nature of preliminary injunctions. That factor does not become more important because the defendants have argued it as a separate Point in their Brief.

Second, even if the defendants ultimately prevail on the merits after injunctive relief is granted, the recall of the adulterated product at the consumer level will have had no negative effect. The defendants will not be correcting the adulterated product to make it compliant with the FDCA and then placing it back into the marketplace. Therefore, regardless of who prevails on the merits, broadening the recall to the consumer level will remove an adulterated product from the market and from the public's hands. As noted above, the FDA has emphasized the importance of removing adulterated pills from the public in its Court filings on similar cases. (See Exhibit "O" attached to the Gainey Reply Declaration.).[13]

Can the defendants really argue to this Court with a straight face that it would be better to leave the adulterated product in the hands of American consumers? Such a statement is ludicrous and it becomes even less credible when you consider that the defendants have resumed production of Atorvastatin, which means identical pills will be on the market to be confused with the adulterated ones that the defendants want to leave in consumers' hands. That was the exact point made by the FDA in its Amicus Brief in *Clark*.

If the defendants prevail on the merits, they will avoid paying compensatory damages, treble damages, attorney's fees and other damages, which leaves the majority of the final relief sought in the plaintiffs' Complaint to be decided after the injunctive relief is granted.

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[13] The FDA also informs companies like Ranbaxy in its Model Letter to Recalling Firms of the "greater chance of accidental misuse" when a defective product is held for a longer time period. (See Exhibit "T" attached to the Gainey Reply Declaration.)

III. THE PLAINTIFFS HAVE SATISFIED THE STANDARD FOR INJUNCTIVE RELIEF

A. The Likelihood Of Success On The Merits

The defendants argue that: (1) the fact that the defendants and the FDA both determined that the defendants' Atorvastatin pills are "adulterated" is not important because there is no private cause of action under the Food, Drug, and Cosmetic Act; and (2) the plaintiffs' motion does not provide specific details of how they will prevail on the claims in the Complaint. In reality, the fact that the defendants have admitted that their product is "adulterated", and that the FDA determined it as well, is sufficient proof for the plaintiffs to prevail on most of the causes of action in the Complaint.

The defendants correctly state that there is no private cause of action under the FDCA. That is precisely why the plaintiffs did not assert a claim under the Act.[14] However, the fact that the defendants' product is "adulterated" as defined under the FDCA is admissible on the claims that are asserted in the plaintiffs' Complaint. The admission by the defendants that the product was "adulterated" and in violation of the FDCA, and confirmation of that by the FDA, is sufficient to establish a prima facie case on the negligence count and the six breach of warranty claims.[15] Put simply, there were glass particles in the prescription pills sold to consumers to be ingested, which is sufficient to support those seven counts in the Complaint even if somehow it is determined that the product is not "adulterated" under the FDCA.[16] The defendant's opposition papers are silent on how

[14] While there is no private cause of action for a violation of the Federal Food, Drug and Cosmetic Act, there is civil liability for a violation of the New Jersey Food, Drug and Cosmetic Act. A claim under that State Statute may be added to the Complaint after the current motion practice and plaintiffs request that the Court consider that when deciding this motion.

[15] The New Jersey Consumer Fraud Act claim and the other fraud claims will be supported, in part, by evidence obtained in discovery, including the defendants' lies, misrepresentations, and falsification of data and documents.

[16] The defendants make the absurd argument that the pills containing glass particles are not dangerous because the definition of "adulterated" in the FDCA does not "suggest that a product that is "adulterated" is necessarily dangerous." We can only assume that the defendants believe that pills which are "adulterated" by glass particles and in violation of the FDCA are not dangerous *per se*. That belief does not bode well for the American public, who are being inundated by generic prescription pills made in foreign plants by companies like Ranbaxy, with its horrific history of lies, deceit, misrepresentations and falsified documents. (See Consent Decree between FDA & Ranbaxy, discussed in Exhibit "K" to Gainey Declaration in Support of the Plaintiffs' initial motion papers.)

they intend to rebut the evidence of glass in the pills and how they will defeat a likely Summary Judgment Motion in the future on those counts.

The defendant's final argument against the plaintiffs' likelihood of success on the merits is to attack the plaintiffs' declarations and the credibility of the plaintiffs.[17] The defendants dismiss the injuries described in most of the Declarations as being "common side effects". Of course, their position ignores the fact that the plaintiffs' medical problems only occurred at the time that they ingested the adulterated pills with glass particles in them. More importantly, the defendants ignore the dozens (more than 50) reports of adverse health events that the FDA has received relating to the adulterated pills. (See Exhibit "Q" to the Gainey Reply Declaration.) Surely, the defendants were aware that such a high number of injuries have been reported to the FDA in light of their claims that they are "working closely with the FDA". The news reporter that obtained the records of the more than 50 injuries had to file a FOIA request but the defendants had direct access to the recall investigation.[18] One can only wonder why the defendants did not mention the high number of injuries reported to the FDA in their opposition papers. Instead, they chose to pretend that there are no reported claims based upon the FDA not receiving any reports "as of November 30, 2012", which is three months ago. (See Ranbaxy Defendants' Memorandum of Law, Page 8) Such games and deceit have come to be expected from Ranbaxy with their tainted past of repeated FDCA violations and related lies.

It is also interesting that the defendants are quick to conclude that Ms. Young's reports of serious injuries are not credible based on the size of the glass particles in the adulterated pills. They do not call for deference to the FDA and its "intense medical analysis" when it comes to Ms. Young's serious and permanent injuries. Instead they offer an unsupported conclusion from counsel about the

[17] The Declarations that were submitted with plaintiffs initial motion papers contained format errors (the "under penalty of perjury" language required under 28 U.S.C. § 1746 was mistakenly omitted). They are being replaced by new Declarations with the proper language.

[18] The plaintiffs are awaiting receipt of a response to their own FOIA request.

credibility of the reported injuries. In reality, the common-sense, reasonable conclusion to be reached, which does not require intense medical analysis, is that ingestion of glass particles is unhealthy and can cause medical problems.

All of the smoke screens and distractions offered by the defendants cannot change the fact that it is very likely that the plaintiffs will prevail on the merits based on the obvious nature of the adulterated pills.

B. Irreparable Harm

The defendants argue that the irreparable harm factor has not been satisfied because: (1) most of the injuries to the public probably happened in the past; and (2) future injuries to consumers will not be life-threatening ones and they can be compensated with a simple payment of money. Both arguments fail.

With the defendants' first argument, they hope to benefit from their intentional delay on the recall and their quiet announcement about the adulterated pills. Since the date that the public finally learned of the adulterated pills, more than 50 reports of injury have been filed with the FDA, which the defendants refuse to acknowledge exist. That large number of cases was reported through February 5th, which is the date of the FOIA response. By the time this motion is argued, another month will have passed with an unknown number of additional adverse health reports. Yet the defendants, without providing any basis, have concluded that "any injury almost certainly occurred in the past". (See Defendants Brief, Page 25).

Even if it was true that the number of reported injuries is decreasing over time, it is not persuasive on the issue of irreparable harm. Consumers who are not aware of the limited recall may not even know the cause of medical problems they are having. A broadened recall would result in more consumers learning of the adulterated product. Once again, the FDA warns firms like Ranbaxy about the chance of accidental misuse increasing the longer that the recalled product is not returned and

destroyed. (See Exhibit "T" attached to the Gainey Reply Declaration.) Thus, the defendants "don't cry over spilt milk" approach is not persuasive or appropriate.

The defendants' second argument against irreparable harm has twisted the case law into what is essentially a modern day equivalent of Ford's infamous memo about the defective Pinto. The case law which holds that injunctions are intended to prevent harm that cannot be compensated by monetary damages later does not mean that the Courts will stand by as additional American consumers are injured by adulterated products made in foreign factories simply because they can be compensated later with money. Broadening the recall to the consumer level would prevent future injuries, which this Court should aim for, even if the injuries are not "life-threatening".[19] The irreparable harm to an unknown number of people in the future, albeit not life threatening, can be and should be avoided by granting the injunctive relief requested.

C. Greater Harm To The Non-Moving Party

The defendants argue that they will suffer irreparable harm if the recall is broadened to the consumer level. Their alleged harm is described as the expense of the recall and injury to its reputation and consumer good will.[20] The defendants rely on *Kos Pharmaceuticals, Inc. v. Andrx Corp., 369 F. 3d 700, 728 (3d Cir. 2004)*. A review of the *Kos Pharmaceuticals* decision by the Third Circuit reveals that the defendants' argument is flawed.

The Court in *Kos Pharmaceuticals* noted that a defendant cannot claim to be harmed when it brought the difficulties and alleged harm on itself. *Id. at 728.* The Court's ruling is particularly applicable to this matter:

> "Injury to goodwill does constitute irreparable harm. *See, e.g., Opticians, 920 F. 2d at 195*. But, when the potential harm to each party is weighed, a party "can hardly claim to be harmed [where] it brought any and all difficulties occasioned by the issuance of an injunction upon itself." *Id. at 197* (directing

[19] The defendants quote the plaintiffs Brief, which states that the "possible adverse health effects are not viewed as life-threatening". (Defendants Brief, Page 27). Certainly the standard should not be set so low for a Company like Ranbaxy, with such a history of violations and cover-ups.

[20] Based on the defendants' past record, it is hard to imagine how their reputation could be more damaged that it is already.

> entry of preliminary injunction). We have often recognized that "the injury a defendant might suffer if an injunction were imposed may be discounted by the fact that the defendant brought that injury upon itself." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 290 F. 3d 578, 596 (3d Cir. 2002).*"

Kos Pharmaceuticals, Inc. v. Andrx Corp., 369 F. 3d, supra at 728 (3d Cir.2004)

In this case, any harm to the defendants as a result of broadening the recall to the consumer level will have been brought upon themselves. It cannot outweigh the irreparable harm to the plaintiffs and the class members.

D. The Public Interest

The defendants argue that the injunctive relief requested would actually harm the public interest. However, it is clear from the defendants' actions, and from their opposition papers, that they are really concerned about their interests rather than the public interest.[21] It is inconceivable that the removal of all of the adulterated pills from the public could be "harmful" to the public interest. In reality, broadening the recall to the consumer level would greatly decrease the likelihood of future harm and problems, many of which become more likely as more time passes. (See FDA Amicus Brief and Model Letter to Recalling Firms, attached as Exhibit "O" and Exhibit "T" respectively to the Gainey Reply Declaration.) Finally, when the fact that the defendants have resumed production of Atorvastatin pills is considered, and the resulting confusion between the adulterated pills and the newly issued ones, it is clear that broadening the recall to the consumer level would best serve the public interest.

III. CONCLUSION

[21] The defendants concerns about the expense of the recall and damage to their reputation was discussed in Point III, C above. Of course, those types of self-inflicted wounds, along with all of their others from their past, are not given serious consideration by the Courts. (See *Kos Pharmaceuticals* and other cases discussed above).

For the reasons set forth in plaintiffs' moving papers and herein, the Court should grant the plaintiffs' motion for a preliminary injunction and issue an order directing the defendants to broaden the recall to the consumer/patient level.

Dated: February 27, 2013

Respectfully yours,

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